

Remarks:

In the November 12, 2010, Office Action, Claims 1-10, 12-17, 19-22, and 24-38 were rejected under 35 U.S.C. Section 112, first paragraph, as failing to comply with the written description requirement.

On the merits, the Examiner rejected Claims 1-10, 12-17, 19-22, 24-28, and 33-38 under 35 U.S.C. Section 103(a) as being unpatentable over Fuchs et al. (U.S. Patent Application Publication No. 2002/0044988) in view of in view of Myllymäki et al. (U.S. Patent No. 5,312,636) and Alltech (believed to be a web page entitled "Alltech to Exhibit Range of Natural Products At Space 2002" and bearing a date of August 7, 2002, but printed on a date which is illegible), and optionally further in combination with either Hallfrisch et al. ("Diets Containing Soluble Oat Extracts Improve Glucose and Insulin Responses of Moderately Hypercholesterolemic Men and Women," Hallfrisch et al., *The American Journal of Clinical Nutrition*, 1995, Vol. 61, pages 379-384) or Van Lengerich et al. (U.S. Patent Application Publication No. 2003/0153746). Claims 29-32 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Fuchs et al. in view of Myllymäki et al. and Alltech, and optionally further in combination with either Hallfrisch et al. or Van Lengerich et al, and further in view of Bengmark et al. ("Gastrointestinal Surface Protection and Mucosa Reconditioning," Bengmark et al., *Journal of Parenteral and Enteral Nutrition*, September, 1995, Vol. 19, No. 5, pages 410-415).

**Section 112 Rejection**

With regard to the alleged 35 U.S.C. Section 112, first paragraph, written description rejection, the Examiner appears to have conflated the written description requirement of 35 U.S.C. Section 112 with the enablement requirement of Section 112. On page 3, lines 6-8 of the November 12, 2010, Office Action, the Examiner stated that "[t]he specification gives no guidance to one of ordinary skill in the art regarding any 'enhancement of growth and/or strengthen the immune system of equine foals.' The specification does not describe 'protein concentrate supplement.'" This is not a written description issue, but rather raises the question of enablement, that is whether or not the patent application enables one skilled in the art to practice the invention as claimed.

First, Applicants object to the raising of an alleged Section 112, first paragraph, rejection at this late date, **over six and one-half years after this patent application was filed**, and after **not raising this issue in the first FIVE office actions**. The issues raised have been present in the claims **since they were filed**. Claim 1 as originally filed read as follows:

1. A nutritional product for equine foals and other animals, comprising:  
a polar lipid supplement which is high in galactolipids and  
antioxidants;  
a soluble fiber that exerts a beneficial effect on health;

a nutritine which **enhances growth and/or strengthens the immune system**; and  
**a protein concentrate supplement.**

Emphasis added. Applicants submit that it is entirely inappropriate for the Examiner to make the Section 112, first paragraph, rejection in the sixth office action allegedly on issues that have been present in the claims since the patent application was filed in 2004. This patent application has been pending for close to seven years and has been subject to five previous office actions without a hint that any of the claims were not described or enabled. It was only when Applicants **narrowed** the claims that the Examiner decided that the claims were not enabled. This is at best a significant violation of the principles of compact prosecution.

Even more significant, in both of these allegations, the Examiner is entirely incorrect, and appears to have ignored the specification. Regarding the Examiner's allegation that "[t]he specification does not describe 'protein concentrate supplement,'" one only needs to look at paragraphs 0065 through 0067 of the specification to learn the following:

1. "The protein supplement used in the nutritional product is whey protein concentrate, which is the product resulting from the ultrafiltration of raw liquid whey and its subsequent evaporation and spray drying to a powder." Paragraph 0065, lines 4-8; and

2. "There are a large number of sources for whey protein concentrate, one example of which is the Volactive Functional Food Products division of Volac International Ltd., of Hertfordshire, U.K., which sells whey protein concentrate under the IMUNOPRO name." Paragraph 0067, lines 1-5.

Thus, it is readily apparent that the Examiner's allegation on this point is unfounded.

Regarding the Examiner's allegation that "[t]he specification gives no guidance to one of ordinary skill in the art regarding any 'enhancement of growth and/or strengthen the immune system of equine foals,'" the specification is replete with very detailed information in paragraphs 0061 through 0091. Paragraph 0061 teaches the basic components of the nutritional product. Paragraphs 0062 through 0079 teach the details of the various components of the nutritional product, including examples of the particular components and in some cases even sources for them. Paragraphs 0080 through 0087 teach the ranges of each component that may be used in the nutritional product. Paragraphs 0088 through 0090 teach the various manners of administering the nutritional product.

Once again, it is readily apparent that the Examiner's allegation on this point as well is quite clearly incorrect. For these reasons alone, the Section 112, first paragraph, rejection must be withdrawn.

Further, the Examiner bears the burden of establishing that practicing the full scope of the claimed subject matter would have required undue experimentation. See *In*

*re Wright*, 999 F.2d 1557, 1561-62, 27 USPQ2d 1510, 1513 (Fed. Cir. 1993), which states that "the PTO bears an initial burden of setting forth a reasonable explanation as to why it believes that the scope of protection provided by that claim is not adequately enabled by the description of the invention provided in the specification of the application."

Moreover, the Examiner's focus on the purported lack of working examples in the present specification is in error as "[working] examples are not required to satisfy section 112, first paragraph." *In re Strahilevitz*, 668 F.2d 1229, 1232 (CCPA 1982). For example, in *Falkner v. Inglis*, the Court affirmed the Board's conclusion that claims to a modified pox virus vaccine were enabled, despite the fact that the specification focused on viruses other than pox virus, provided no examples directed to pox virus, and discussed pox virus only in general terms relating to the inventive disclosure. *Falkner*, 448 F.3d 1357, 1365 (Fed. Cir. 2006). Thus, as noted in *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313 (Fed. Cir. 2003):

"The enablement requirement is often more indulgent than the written description requirement. The specification need not explicitly teach those in the art to make and use the invention; the requirement is satisfied if, *given what they already know*, the specification teaches those in the art enough that they can make and use the invention without 'undue experimentation.'"

*Id.* at 1334 (emphasis added). Accordingly, Applicants believe that the 35 U.S.C. Section 112, first paragraph, rejection is without merit and must be withdrawn.

### **Section 103(a) Rejections**

The Section 103(a) rejections are defective in their entirety in that they rely upon the Fuchs et al. reference as the principal reference. The Examiner has either overlooked the amendment previously made to Claim 1 in Applicants' October 19, 2010, Amendment C, or has misunderstood Applicants detailed explanation of the deficiency of the Fuchs et al. reference with respect to the claims that was provided in Applicants' October 19, 2010, Amendment C. Applicants' explanation from their October 19, 2010, Amendment C is hereby incorporated into this Response in its entirety.

There are two salient facts that destroy the applicability of the Fuchs et al. reference to the claims:

1. Claim 1 was amended in the Applicants' October 19, 2010, Amendment C to require that the "soluble fiber source is derived from **at least one ingredient selected from the group consisting of oats, barley, and soybeans.**" Emphasis added. Thus, each and every pending claim in the present patent application requires the presence of a "soluble fiber source that has been fractionated from its natural origin which soluble fiber source exerts a beneficial effect on health, wherein said soluble fiber source is derived from **at least one ingredient selected from the group consisting of oats, barley, and soybeans.**" Emphasis added.
2. The Fuchs et al. reference **specifically excludes the use of a fiber that would induce satiety.** This subject was discussed in considerable detail in Applicants'

October 19, 2010, Amendment C. Paragraphs [0046] and [0048] of the Fuchs et al. reference requires that the supplement of that reference is to have a "soluble, prebiotic fiber" with the requirement that "[t]he fiber selected **should not induce satiety**." Fuchs et al. reference, Paragraph [0051], emphasis added. Each and every one of Applicants' claims requires that the "soluble fiber source is derived from at least one ingredient selected from the group consisting of oats, barley, and soybeans," and each of these ingredients are known to induce satiety, as was conclusively established in Applicants' October 19, 2010, Amendment C.

In summary, Applicants have satisfactorily established that each of oats, barley, and soybeans does in fact induce satiety:

1. "It is well known that oats and, particularly, the soluble fibre in oats (beta-glucan) **induce high levels of satiety**." Optimising Cardio Health With Oat Beta-Glucans, Gregory Stephens, *Functional Ingredients Magazine*, April 1, 2005, <http://www.functionalingredientsmag.com/article/Ingredient-Focus/optimising-cardio-health-with-oat-beta-glucans.aspx>, of which a copy was enclosed with the Applicants' October 19, 2010, Amendment C, emphasis added. Stephens goes on to state that "beta-glucan from oats **and other grain sources** are highly water soluble and thus build substantial viscosity in the gut." Emphasis added.
2. "[B]arley beta glucans **are an effective way of enhancing satiety** and reducing energy. . . . Studies have demonstrated that **incorporating barley beta glucans**

- in food formulations induces satiety. . .**" Peter M. Schkoda, Barley Beta Glucans Application in Obesity, supplement to AgroFOOD industry hi-tech, September/October 2008, Vol. 19, No. 5, of which a copy was enclosed with the Applicants' October 19, 2010, Amendment C, emphasis added.
3. "[D]emand for products that offer satiety benefits and a low glycemic index is growing. In this regard, **soy protein fits the bill because it's naturally satiating** and offers a low glycemic index." Soy Protein Applications, *Protein Foods and Nutrition Development Association of India*, March, 2005, Pages 9-11, of which a copy was enclosed with the Applicants' October 19, 2010, Amendment C, emphasis added. "Soybean has **an exceptionally high satiety value**." Ishi Khosia, Soybean – the Golden Nugget, *Indian Express*, April 22, 2006, <http://www.indianexpress.com/news/soybean-the-golden-nugget/2915/>, of which a copy was enclosed with the Applicants' October 19, 2010, Amendment C, emphasis added.

Thus, since the Fuchs et al. reference **specifically excludes the use of a fiber that would induce satiety**, the Fuchs et al. reference thereby **specifically excludes the use of any of oats, barley, and soybeans as fibers**, since each of these fibers have been demonstrated to produce satiety.

It is thus readily apparent that the Examiner has misapprehended Applicants' arguments in the October 19, 2010, Amendment C. The Examiner states that "the



features upon which applicant relies (i.e., the fiber selected should not induce satiety) are not recited in the rejected claim(s)." November 12, 2010, Office Action, page 16, lines 17-18. In so saying, the Examiner has missed the point entirely.

The Fuchs et al. reference requires that the fibers used in the Fuchs et al. supplement do not induce satiety. Applicants have required in their claims that the soluble fiber source is derived from "**at least one ingredient selected from the group consisting of oats, barley, and soybeans,**" each of which has been demonstrated to produce satiety. Since the Fuchs et al. reference requires fibers that do not induce satiety, the Fuchs et al. reference teaches directly away from Applicants claims. This is the case with respect to every single claim pending in the present patent application.

Further, the Examiner reasons that the supplement of the Fuchs et al. reference is to "enable patients with digestive tract problems to retain their strength quickly and to help recovery of convalescing patients," citing paragraph [0022] of Fuchs. That paragraph in its entirety reads:

"Remarkably, because of the nature of the whey protein and the facts that it increases protein synthesis and it is capable of being easily digested, the composition has a beneficial effect in persons requiring a nutritional supplement such as those suffering from muscle mass depletion **and/or with limited appetite**, such as those suffering or recovering from trauma, illness, or surgery, the elderly or those who have problems digesting other sources of protein such as persons having chronic gastritis who are known to have a reduced gastric pepsin digestion. Remarkably, the composition enables such persons to retain or regain their strength quickly and therefore helps aid recovery of a convalescing patient."

Emphasis added. Thus, when the Fuchs et al. reference states that the soluble probiotic fiber should not induce satiety, it means it, as including soluble fibers that induce satiety as featured in the present claims would result in a supplement that dulls the patient's appetite. Thus, the examiner's proposed combination of references is in direct contravention of the purpose of the Fuchs et al. reference.

Where the teachings of two or more prior art references conflict, the examiner must weigh the power of each reference to suggest solutions to one of ordinary skill in the art, considering the degree to which one reference might accurately discredit another. *In re Young*, 927 F.2d 588, 591 (Fed. Cir. 1991). If the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 902 (Fed. Cir. 1984). Further, the Federal Circuit has held that "[a] reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 (Fed. Cir. 1994); *Para-Ordnance Mfg., Inc. v. SGS Importers Int'l, Inc.*, 73 F.3d 1085, 1090 (Fed. Cir. 1995).

Thus, the rejections using the Fuchs et al. reference are deficient in fact and law. As such, the Section 103(a) rejections in the November 12, 2010, Office Action are in

error, and must be withdrawn. Applicants believe that the claims of the present patent application are clearly allowable as being distinguished from the cited prior art.

**Conclusion**

Claim 1-10, 12-17, 19-22, and 24-38 remain pending. Reconsideration of the claimed subject matter is respectfully requested, with an early and favorable decision being solicited. Should the Examiner believe that the prosecution of the application can be so expedited, the Examiner is requested to call Applicants' undersigned attorney at the number listed below.

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